

Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants

SOPP 8101.1

Appendix 1

Example of Meeting Scheduling Memo

Applications Division name

Our Reference: *tracking #*
(*IND, BLA, CRMTS, etc.*)

Request received *date*

Requestor *Requestors name*
Requestor's affiliation

Meeting type *(pre-IND, End of Phase 2, etc.)*

Meeting Schedule:

Date:

Time:

Location: *office building, conference room,*
exact address

Tentative CBER attendees:

Please note that pre-read materials need to be submitted at least *2 weeks/Type A or C or 1 month/Type B* prior to the scheduled meeting date. Please submit ____ copies of the pre-reads.

Due Date for receipt of meeting pre-reads at *Division name*: _____

Please note that a productive meeting depends on the timely receipt of adequate pre-read materials. Consequently CBER may cancel the meeting if the above conditions are not met.

If you have any questions, please contact *Point Of Contact* at *telephone number*.